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Blockchain in the Pharmaceutical Industry

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ABSTRACT

Blockchain is a decentralized peer-to-peer distributed network ledger and the architecture of a new Internet. It is a digital ledger that records transactions and information in a highly secure and transparent manner. It has already made a big impact in other industries, such as finance and logistics, and it is now poised to disrupt the pharmaceutical industry. Blockchains in the pharmaceutical industry can securely record data in real-time and protect it from being altered in the future. It has played the role of revolutionizing transparency and traceability within the pharmaceutical industry. In this paper, we focus on the adoption of blockchain technology in the pharmaceutical industry.

KEYWORDS: *blockchain, pharmaceutical industry, pharma*

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INTRODUCTION

Blockchain is a distributed ledger technology that allows for secure, transparent, and tamper-proof transactions. It may be regarded as the technological revamp of the public ledger. Blockchain technology has gained significant popularity in various industries, including finance, healthcare, and supply chain management. Blockchains in the pharmaceutical industry can securely record data in real-time and protect it from being altered in the future. Figure 1 shows the symbol of blockchain [1].

Within the United States, pharmaceuticals account for a growing share of the healthcare economy. The pharmaceutical industry encompasses several key internal stakeholders, including pharmaceutical manufacturers, pharmaceutical wholesalers, health systems, pharmacies, and individual patients with prescription needs. The industry also has several external stakeholders that include the general public, government entities that oversee and regulate the industry, and accreditation and trade organizations. Numerous companies and organizations are utilizing blockchain technology to revolutionize the pharmaceutical industry [2].

WHAT IS BLOCKCHAIN?

Blockchain, a type of distributed digital ledger technology (DLT), is a relatively new and exciting way of recording transactions in the digital age. It is a decentralized and distributed digital ledger technology that securely records and verifies transactions across multiple computers or nodes in a network. Basically, it is a chain of blocks in which each block contains a list of transactions. The blockchain technology was created as the foundational basis for Bitcoin – a digital currency in which secure peer-to-peer transactions occur over the Internet. It is expected that the spending on blockchain solutions worldwide would grow from 4.5 billion USD (2020) to an estimated value of 19 billion USD by 2024 [3].

Originally developed as the accounting method for the virtual currency Bitcoin, Blockchains are appearing in a variety of commercial applications

today. Blockchain technology is a type of distributed digital ledger that uses encryption to make entries permanent and tamper-proof and can be programmed to record financial transactions. It is used for secure transfer of money, assets, and information via a computer network such as the Internet without requiring a third-party intermediary. It is now being adopted across financial and non-financial sectors. As a catalyst for change, the Blockchain technology is going to change the business world and financial matters in major ways.

The first Blockchain was conceived in 2008 by an anonymous person or group known as Satoshi Nakamoto, who published a white paper introducing the concept of a peer-to-peer electronic cash system he called Bitcoin [4,5]. Bitcoin and Ethereum are the first two mainstream blockchains. Other modern blockchains include Namecoin, Peercoin, Ether, and Litecoin. Figure 2 shows different components of blockchain [6].

Blockchain combines existing technologies such as distributed digital ledgers, encryption, immutable records management, asset tokenization and decentralized governance to capture and record information that participants in a network need to interact and transact. As illustrated in Figure 3, a complete blockchain incorporates all the following five elements [7]:

- *Distribution:* Digital assets are distributed, not copied or transferred. A protocol establishes a set of rules in the form of distributed mathematical computations that ensures the integrity of the data exchanged among a large number of computing devises without going though a trusted third party. A centralized architecture presents several issues including a single point of failure and problems of scalability.
- *Encryption:* BC uses technologies such as public and private keys to record data securely and semi-anonymously. Completed transactions are cryptographically signed, time-stamped, and sequentially added to the ledger.
- *Immutability:* The Blockchain was designed so these transactions are immutable, i.e. they cannot be deleted. No entity can modify the transaction records. Thus, Blockchains are secure and meddle-free by design. Data can be distributed, but not copied.
- *Tokenization:* Value is exchanged in the form of tokens, which can represent a wide variety of asset types, including monetary assets, units of data or user identities.
- *Decentralization*: No single entity controls a majority of the nodes or dictates the rules. A consensus mechanism verifies and approves transactions, eliminating the need for a central intermediary to govern the network.

Bitcoin and its underlying blockchain technology increasingly impact all facets of society. Bitcoin's status as digital gold is merely the tip of this technology. Figure 4 shows Bitcoin [8]. Although blockchain technology will for all time be associated with Bitcoin due to their common genesis, it has broader applications. Cryptocurrency will increasingly become a factor in family law issues as well.

A blockchain is a tamper-proof, distributed database that stores blocks of information for cryptographically bound transactions via peer-to-peer networks. At the heart of blockchain's functionality is cryptographic hashing. Each block in a blockchain contains a cryptographic hash of the previous block, creating an immutable chain of blocks. If anyone attempts to tamper with the data in a block, it would alter the block's hash. This would disrupt the entire chain, making it virtually impossible to manipulate. The security feature ensures data integrity and prevents unauthorized changes [9].

In a nutshell, blockchain technology involves three basic concepts [10]: (1) It is a system for recording a series of data items (such as transactions between parties); (2) It uses cryptography to make it difficult to tamper with past entries; (3) It has an agreed process for storing copies of the ledger and adding new entries (also called a consensus protocol).

BLOCKCHAIN IN PHARMACEUTICAL

Blockchain is a decentralized, distributed ledger that records transactions across a network of computers. It can be viewed as a distributed ledger that is a permanently recorded set of data that is incorruptible. Blockchain technology does not depend on a centralized authority. Instead, each record is accessible to all members of a blockchain and can be easily verified. Since the invention of the cyber currency, Bitcoin, blockchain technology has been implemented across many industries to solve a plethora of problems.

A blockchain is a software that offers a digital ledger system to record and log transactions by chronologically combining them into ordered blocks. The blockchain technology is accelerating digital transformation across multiple industries, including the pharmaceutical industry. When we speak of the pharmaceutical sector, we mean these three things: distribution, development, and discovery process.

Blockchain is an emerging technology that is expected to open up a promising future for various industries, especially for the pharmaceutical industry, which is a critical part of healthcare. Blockchain technology, with its shareable ledger and immutable data, is ideally suited to the task of tracking unique digital IDs assigned to product units and identifying the location of products under recall in seconds, not days. Figure 5 shows a representation of blockchain in Pharmaceutical Industry [11].

APPLICATIONS OF BLOCKCHAIN IN PHARMACEUTICAL

Blockchain technology is a distributed ledger that enables the efficient, permanent, and verifiable recording of transactions. Blockchains are used in the pharmaceutical industry for different purposes. Figure 6 displays blockchain applications in the medical field, including pharmaceuticals [12]. The blockchain application areas covered here include supply chain, drug manufacturing, counterfeit drug prevention, healthcare, security, tracking and tracing, and clinical trials [13,14].

- *Supply Chain:* In any industry, it is important to manage the supply chain, but in the pharmaceutical industry, the stakes are at their peak. The pharmaceutical supply chain is complex and filled with challenges, from counterfeiting and diversion to transparency and traceability issues. Modern pharma supply chain systems are complicated, involving manufacturers, suppliers, and consumers that span across continents. The pharma supply chain comprises various parties including distributors, manufacturers, raw material suppliers, regulators, pharmacies, hospitals, and patients. Due to the product's complexity and transaction flows, an efficient traceability system is needed in the pharma supply chain to identify the current and all previous product owners. Disruptions along the pharma supply chain are not just an inconvenience, they can cost people their lives. But blockchain is a new technology on the horizon that has the potential to revolutionize the way we manage pharma supply chains. One of the most pivotal applications of blockchain in the pharmaceutical industry is enhancing supply chain integrity. Blockchain technology is a transformative force in the pharmaceutical supply chain. It has the potential to significantly improve vaccine supply chain management in a number of ways. It can enable real-time tracking of vaccines from the point of manufacture to the point of administration. The primary advantage of blockchain in the supply chain for the pharma industry is its ability to provide end-to-end traceability, ensuring that the journey of pharmaceutical products can be tracked from their origin to the hands of patients. The success of blockchain in the pharmaceutical supply chain depends on well-defined data governance rules. These rules determine who can access and modify data, ensuring that only authorized personnel can make changes.
- *Clinical Trials:* Clinical trials track the interactions of a pharmaceutical within a given population. If the results are skewed or corrupted, it is more than money on the line. With blockchain, there is a way for all data to be securely recorded and then shared throughout a community. If there is a problem with how the trial was conducted, it is easier for peers to review and confirm the validity of the data. Sensitive data from a clinical trial, such as who is taking a placebo or what type of symptoms a patient develops, can not only be updated in real-time on a blockchain, but it can also be done in a way that minimizes the odds of error. Doctors may even be able to recruit more people to the trial, which can improve the credibility of their findings.
- *Manufacturing:* Drug manufacturers can ensure that drugs are going where they are supposed to go and that each product arrives completely intact. The manufacturers job is to make sure their medicine inventory is ready for distribution to wholesalers. Manufacturers ship their items to distributors warehouses so they can be stored after receiving orders from distributors or wholesalers. Distributors will give manufacturers reports on inventory data in order to keep things transparent all the way through. A typical drug manufacturing is shown in Figure 7 [15].
- *Counterfeit Drugs:* Pharmaceutical drugs are used in the diagnosis, treatment, and prevention of disease. Patients as well as the pharmaceutical industry suffer from the trade of counterfeit drugs, particularly given that these drugs may be ineffective or toxic. Counterfeit drugs are produced outside the legitimate pharmaceutical manufacturing system and, therefore, are fraudulent. Counterfeit drugs are one of the most severe threats to the pharmaceutical industry. Given that counterfeit drugs resemble the original drugs, they can be challenging to detect. In most cases, they are designed to appear identical to the original product and may not cause an obvious or harmful reaction. The use of blockchain technology in the pharmaceutical industry has been identified as a viable way to protect against

counterfeit drug distribution. Blockchains can be used to trace the origin of pharmaceuticals, the transport of drugs, and the procurement of raw materials. Pharmaceutical products are serialized and assigned security features that can be verified by consumers and differentiated from counterfeits. The presence of multiple dealers and intermediaries presents an opportunity for malpractice that undermines supply chain efficiency. Blockchain has been hailed for preventing the circulation of poor-quality pharmaceuticals. Figure 8 shows some drugs [16], while Figure 9 displays some scientists [15].

- *Tracking and Tracing:* An essential focus of the pharmaceutical industry is to ensure rapid and secure transactions, along with supply chain fidelity. Naturally, goods in transit should be tracked and traced from dispatch to destination. The distribution of substandard and counterfeit drugs has led to deaths, prompting government agencies worldwide to implement trace and track systems to oversee pharmacy supply chains. Drug tracking and traceability are essential for business operations, patient health, and regulatory compliance. Stakeholders in the pharmaceutical industry frequently suffer losses *via* theft and loss of goods due to a lack of robust tracking and tracing. Therefore, many organizations in the pharmaceutical industry, as a result of malpractice and poorly functioning supply chains, have sought to employ blockchain technology to harness operations and streamline tracing and tracking, medical transactions, and patient safety.
- *Data Security:* Since drugs are high-value commodities, security is necessary to protect them. Security is bolstered against theft and the introduction of counterfeit pharmaceuticals. The design features of traditional drug supply chain management cannot transmit necessary information safely and reliably. In many cases, data can be deleted, modified, and tampered with easily. Patient data is the cornerstone for a practitioner's course of treatment, though organizing, sharing, and protecting that information has long plagued small clinics and large hospitals alike. Security is a major challenge and is addressed through the use of cryptographic technologies that validate blocks of transactional data. Blockchain uses cryptographic techniques to secure data, enhancing protection against unauthorized access. This is particularly crucial in the pharmaceutical industry to safeguard sensitive patient information and intellectual property. The cryptographic nature of blockchain ensures that once data is added to the ledger, it becomes virtually immutable. This significantly reduces the risk of data breaches, fraud, and unauthorized alterations, making it an ideal solution for protecting sensitive pharmaceutical information.
- *Healthcare:* While spending in healthcare markets may be high, the public's trust in healthcare is relatively low. The blockchain can bolster public trust by cutting down on counterfeit drugs and on drug shortages. In healthcare, the blockchain is a potential solution to protect patient data and manage the complex supply chain of pharmaceuticals. When healthcare organizations transition to the blockchain, even the most dedicated criminals in the world would find it impossible to manipulate its contents.

BENEFITS

Blockchain technology offers multiple benefits for the pharmaceutical industry, making it a compelling choice for supply chain management. One of the advantages of blockchain technology is the inability to change any contracts and transactions that are added to the ledger. Blockchain can be used to track pharmaceutical products at every step of the supply chain, from manufacturing to distribution, and ultimately to the end-user. Some of the features that blockchain technology offers, primarily due to decentralization, are information security and privacy. Other benefits include the following [9,17]:

- *Traceability:* Drug traceability is the process of identifying the originality and legitimacy of drugs by enabling the stakeholders (sellers, manufacturers, wholesalers, pharmacies, and patients) in the drug supply chain to track and trace the flow of transactions executed amongst them. Due to the chronological and unalterable nature of blockchain records, it is possible to trace the entire journey of a product or information. In pharma, this means tracking the origin of raw materials, manufacturing processes, distribution, and even patient usage. Blockchain allows for the complete traceability of pharmaceutical products, from their point of origin to the hands of patients. Every transaction is recorded and timestamped, providing a comprehensive audit trail.
- *Trust:* Blockchain's transparency fosters a high level of trust among all supply chain participants. Each stakeholder can verify the authenticity of transactions, ensuring compliance with regulations and contractual agreements. Trust and transparency are necessary for the pharmaceutical industry because, without trust, the counterfeiting business thrives, exposing the public to dangers

arising from low-quality or substandard pharmaceuticals.

- *Monitoring:* The pharmaceutical industry's ability to monitor goods and products is essential. Given the industry's multifaceted nature, there is a deficiency in authenticating products and preventing prescription misuse. Blockchain technology's inherent lack of central governance can enhance visibility, authentication, and information flow, ultimately improving patient care in the context of pharmaceutical needs. The use of smart contracts is one way that blockchain technology can be used to promote proper supply chain monitoring.
- *Privacy:* The blockchain was designed to help patients maintain their privacy. Patients have the right to be forgotten, which is currently impossible to accomplish with an unchangeable ledger. Not only are there concerns over whether a blockchain platform will satisfy privacy laws, but there are also very few administrators who would want to overhaul their entire networks for it.
- *Patient Safety*: At the heart of every pharmaceutical endeavor lies the well-being of patients. Transparent supply chains and traceable processes ensure that medications are manufactured, stored, and distributed under stringent quality standards, minimizing the risk of compromised products reaching patients. The improvement of drug administration through better supply chain management means better patient access to the right pharmaceuticals.
- *Data Integrity:* In an era dominated by digitalization, maintaining the integrity of data is paramount. Transparent and tamper-proof blockchain records minimize the risk of data manipulation, fostering trust in clinical trials, research, and regulatory submissions. Blockchain's immutability ensures that research findings, patient data, and clinical trial results are recorded accurately and cannot be altered retrospectively.
- *Scalability:* This is a measure of how well a blockchain system can maintain low transaction latency even with an increased number of workloads. This is an important consideration for blockchain systems, as increased workloads can lead to increased transaction processing times and lower system performance. By designing systems that can scale to accommodate higher workloads, blockchain developers can ensure that their systems remain performant and responsive even as demand grows.
- *Regulations:* Regulations like HIPAA have imposed ever stricter laws to ensure practitioners keep their patient's data safe. Even with the restrictions imposed by regulatory bodies, oversight is not always what it should be.
- *Efficiency Gains*: By automating processes through smart contracts, blockchain streamlines supply chain operations. This leads to reduced administrative overhead, faster transactions, and lower costs, ultimately benefiting both the industry and patients.
- *Standardization:* Blockchains can facilitate secure banking transactions globally, but a significant challenge relates to interoperability issues. To standardize blockchain operations, distributed ledger technology (DLT) can be utilized. The International Telecommunication Union (ITU) works to identify and standardize distributed ledger technology (DLT) applications and their services.
- *Personalized Medicine:* Blockchain's capability to securely store and share patient data could facilitate the development of personalized treatment plans. Patients can control access to their medical history, empowering them to contribute to research while safeguarding their privacy.
- *Cold Chains:* Certain medicinal products are stored in the refrigerator all the way from the manufacturing company to the pharmacy. It is referred to as the cold chain. Cold chains are temperature-controlled supply chains and have a high priority from the managerial point of view. Naturally, pharmaceutical cold chains are complex and complicate processes because of requiring the involvement of many stakeholders with essential requirements. The sensitive chains need to be managed effectively based on its direct effects on public health and peoples' life. Blockchain technology is applicable in pharmaceutical cold chain automation and management.
- *Automation:* Blockchain offers smart contracts. Smart contracts offer the ability to automate tasks on the blockchain. This is very useful as the smart contracts can execute notifications if the compliance conditions are not met. Once done, all the parties relevant to the drug will be notified.

CHALLENGES

The pharmaceutical industry faces an array of challenges, including a lack of transparency, difficulty tracking products, lack of trust, and the shipment of expired products. Blockchain technology

has been applied to solve several of these problems. The sheer number of parties involved in pharmaceuticals make for a logistical nightmare for even the most experienced services. Due to massive availability of data, there are many challenges associated with blockchain implementation, including data management, accessibility issues, data redundancy, and data privacy. In spite of the benefits, not everyone is convinced of the blockchain's ability to protect data according to the law. Challenges such as technological complexity, regulatory adaptation, and privacy concerns must be navigated to fully unlock blockchain's potential. Other challenges include the following [9,17]:

- *Cost:* While the benefits of blockchain in the pharmaceutical supply chain are undeniable, it is important to consider the transaction costs associated with its implementation. Blockchain technology requires investment in infrastructure, training, and ongoing maintenance. However, these costs are often outweighed by the long-term gains in efficiency, security, and trust.
- *Counterfeit Drugs*: Counterfeit drugs pose a grave threat to patient safety within the pharmaceutical supply chain. These fake medications can infiltrate the market, potentially causing harm to unsuspecting patients. Blockchain technology provides an immutable and transparent ledger that tracks each pharmaceutical product's journey from production to consumption. This ensures that counterfeit drugs are detected and eliminated from the supply chain, enhancing patient safety.
- *Lack of Transparency:* The lack of transparency in the pharmaceutical supply chain can lead to a multitude of issues, including delayed response to supply chain disruptions and difficulties in monitoring the conditions of pharmaceutical products during transit. The adoption of Internet of things devices and sensors in conjunction with blockchain offers real-time monitoring and transparency. This technology enables stakeholders to trace the movement and conditions of medicines, ensuring visibility and accountability at every stage.
- *Inefficiencies:* Inefficiencies in supply chain operations can lead to delays, increased costs, and waste. Manual processes, paper-based documentation, and redundant administrative tasks can create bottlenecks and slow down the movement of pharmaceutical products. Smart contracts powered by blockchain automate supply chain processes, from inventory management to payments. This reduces administrative overhead, accelerates transactions, and minimizes inefficiencies, resulting in cost savings and streamlined operations.
- *Regulatory Compliance:* The pharmaceutical industry is subject to stringent regulatory requirements to ensure the safety and quality of medications. Meeting these regulatory standards can be challenging, especially when it comes to providing timely and accurate data to regulatory bodies. Blockchain's immutable records facilitate compliance with stringent regulatory requirements. Regulatory bodies can access real-time data, ensuring that pharmaceutical companies adhere to quality and safety standards.
- *Data Security and Privacy:* Protecting sensitive pharmaceutical data from breaches and unauthorized access is paramount. Data breaches can compromise patient privacy and the integrity of the supply chain. Blockchain employs advanced cryptographic techniques to secure data, protecting it from breaches and unauthorized access. Data on the blockchain is highly secure, enhancing data privacy and integrity.
- *Global Collaboration:* The pharmaceutical supply chain is a global network involving multiple stakeholders across borders. Effective collaboration among these stakeholders is essential to ensure timely access to medications for patients worldwide. Blockchain enables secure and efficient data sharing among stakeholders across borders. It fosters international collaboration, ensuring that pharmaceuticals reach patients in a timely and equitable manner.
- *Complex Supply Chains:* Pharma supply chains span the globe, involving multiple intermediaries, making tracking and verifying each step a formidable challenge. Integrating blockchain into existing systems requires technical expertise and resource allocation. Overcoming this hurdle demands collaboration between tech specialists and pharmaceutical professionals.
- *Data Privacy:* While transparency is key, protecting sensitive patient data is equally important. While blockchain enhances transparency, privacy concerns persist. Striking the right balance between transparency and privacy is a delicate task.
- *Interoperability:* Achieving seamless data exchange between different blockchain networks and legacy systems remains a technical challenge that must be overcome.
- *Visibility:* One of the main obstacles that cause concern about fake products, drug shortfalls, and

opiates is a lack of visibility. Patients, dealers, and controllers have little understanding of where medications come from or how they are made. If a drug is tainted throughout manufacturing, the vendor may be asked to solve the problem caused by a lack of transparency. Blockchain technology has emerged as a potent solution to this critical requirement.

- *Stagnation:* Another challenge the pharma industry is suffering from is stagnation. It is because of no change in the strategies, management culture, and mental models. Everything is done in a traditional manner, which does not improve any of the pharma industry's current pain points.
- *Data Discrepancy:* Data is the most crucial and integral part of any working system. Data about new drugs, medicines, etc. form the foundation of the pharma database. This data is used for research and analytics to generate reports about experiments and innovation. Now this data is fetched from multiple silos connecting hospitals, various pharmaceutical companies, research labs, etc. Due to the discrepancy in data, it is not useful for performing any analytics on it as it may generate incorrect reports. Incorrect analysis and erroneous data leads to undesirable generation of drugs which can lead to catastrophic consequences. blockchain in pharma helps eliminate this inconsistency.

Some of these challenges are shown in Figure 10 [12].

CONCLUSION

In this paper, we have explored the potential benefits of using blockchain in the pharmaceutical industry and its operations. The pharmaceutical industry is undergoing massive changes. Historically this industry slows to adopt the technology. In recent years, blockchain technology has made great strides in diverse industries, but it has fallen behind within the pharmaceutical industry. Blockchain technology is emerging as a transformative force in the pharmaceutical sector. It offers robust solutions to long-standing challenges like drug counterfeiting, complex supply chains, and strict compliance demands. It also offers a new and promising solution to the pharmaceutical industry's needs.

As blockchain technology advances, its capacity to address critical challenges in the pharmaceutical industry becomes increasingly evident. Blockchain can modernize the pharma industry as it introduces three important elements in the industry: privacy, transparency, and traceability. More information on the integration of blockchain technology into the pharmaceutical industry is available from the books in [18,19] and in the following related journals:

- *IEEE Blockchain*
- *International Journal of Pharmaceutics*
- *International Journal of Comprehensive and Advanced Pharmacology*

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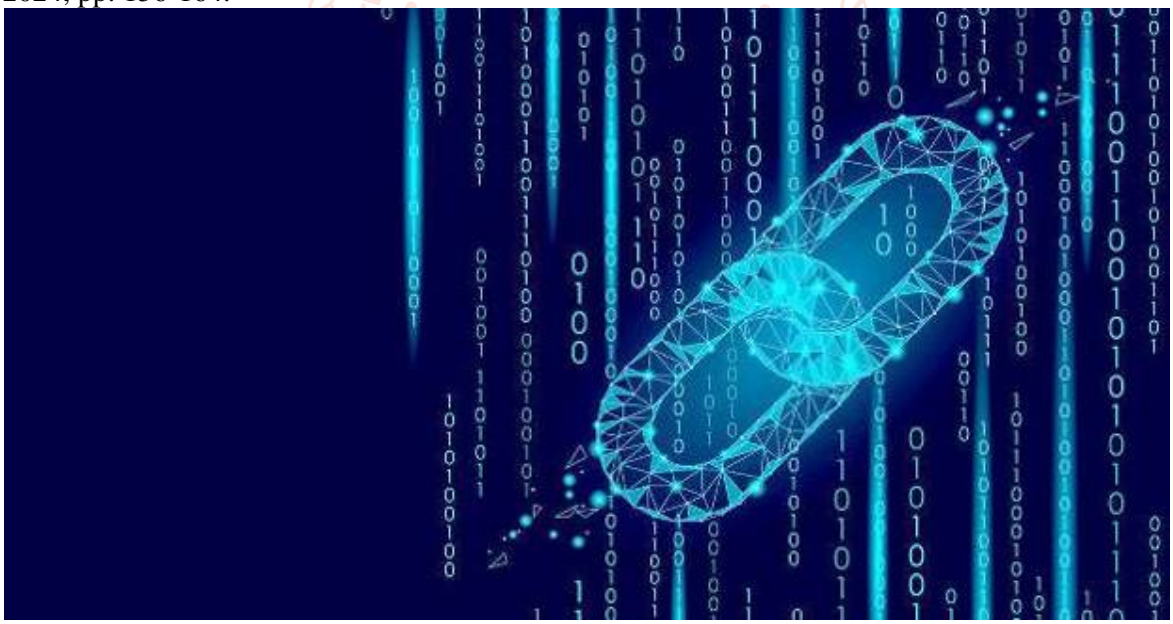

Figure 1 The symbol of blockchain [1].

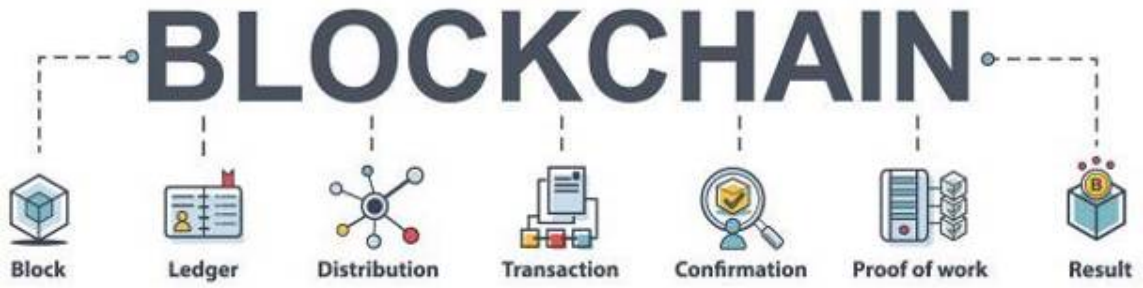

Figure 2 Different components of blockchain [6].

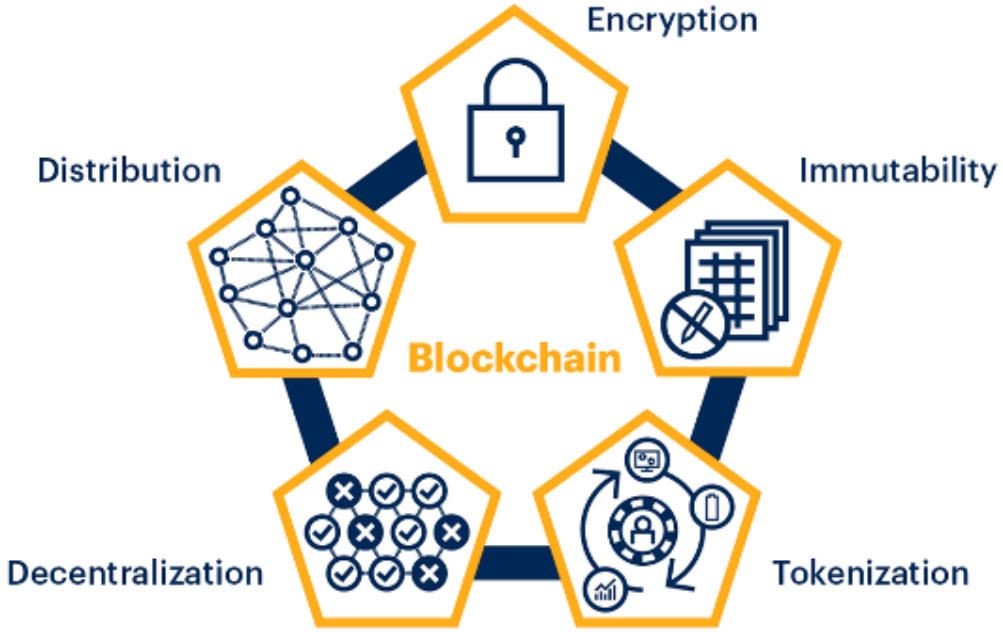

Figure 3 Five key elements of Blockchain [7]. b

Figure 4 Bitcoin [8].

Figure 5 A representation of blockchain in pharmaceutical industry [11].

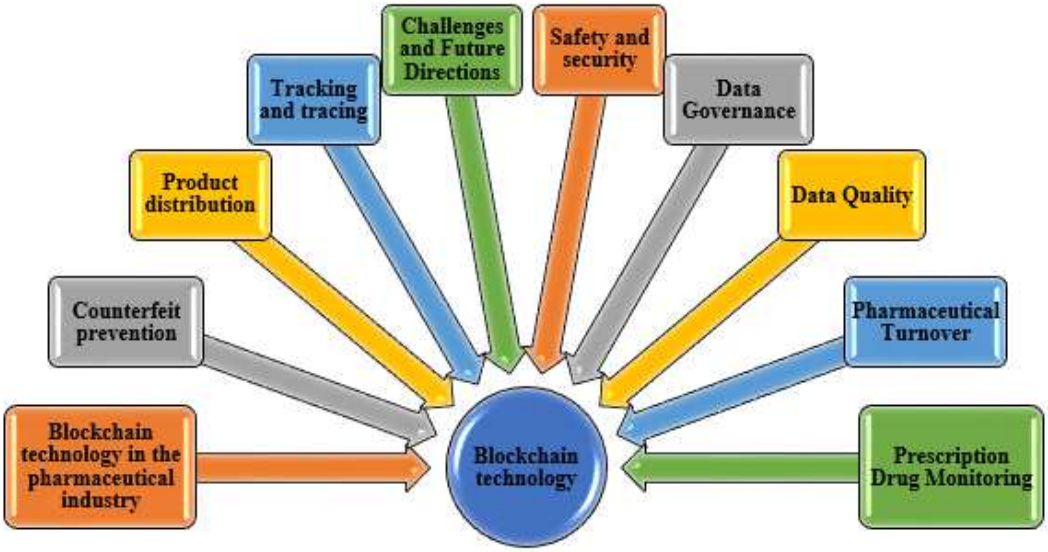

Figure 6 Blockchain applications in the medical field [12].

Figure 7 A typical drug manufacturing [15].

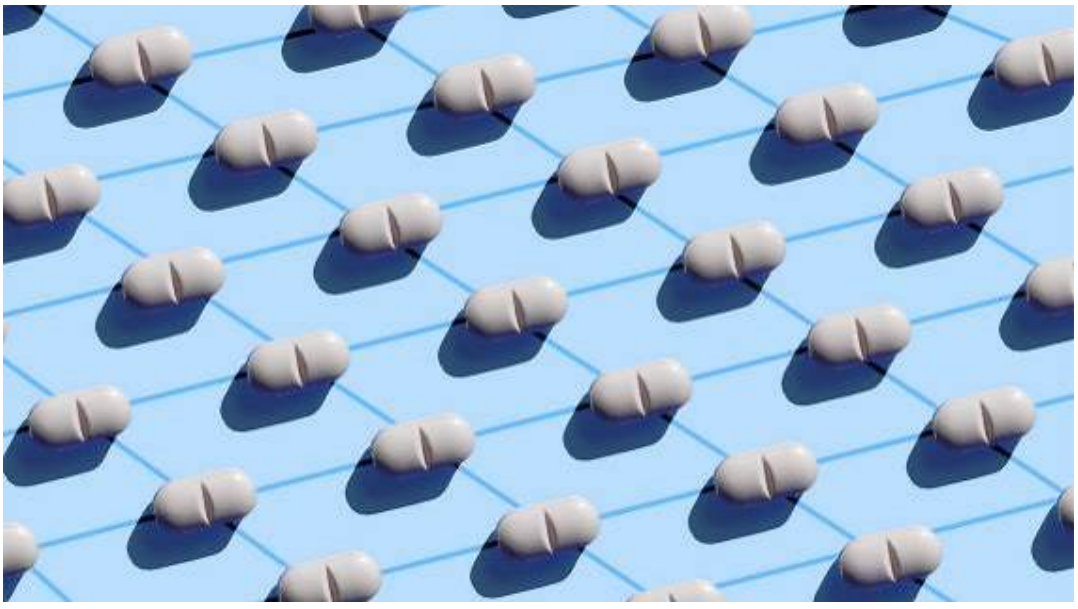

Figure 8 Some drugs [16].

Figure 9 Some scientists [15].

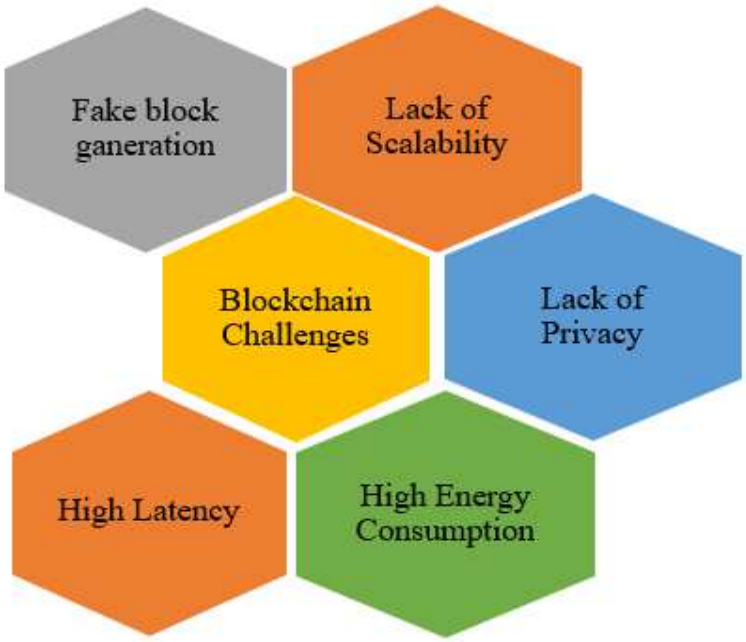

Figure 10 Some of these challenges of blockchain in pharma [12].